K003853

FEB 1 3 2001

SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

1. General Information

Classification:	Class II Magnetic Resonance Imaging (MRI) System
Common/Usual Name:	Magnetic Resonance Imaging (MRI) System
Proprietary Name:	Infinion 1.5T MR Imaging System
Establishment Registration:	Marconi Medical Systems, Inc. World Headquarters 595 Miner Road Highland Heights, Ohio 44143 Contact: Duane Praschan Phone: (440) 483-3000 FDA Owner Number: #1580240 FDA Registration Number: #1525965
Performance Standards:	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The Infinion 1.5T MR Imaging System does not change the existing indications as defined below.

The Infinion 1.5T MR Imaging System is indicated for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

3. Device Description

Marconi's Infinion 1.5T MR Imaging System includes changes in the computer subsystem, gradient subsystem, RF subsystem, magnet subsystem, patient handling subsystem and magnet enclosure. Additional enhancements have also been made in the optional receive-only coils provided with the system and in some of the software options. The main features provided with this system include a fully dockable couch, an improved approach to SAR calculation and body coil to increase patient comfort, a flared

shorter magnet to improve openness of the system, Multi-Mode Array coils and up to eight receive channels.

4. Safety and Effectiveness

The functionality included in Marconi's Infinion 1.5T MR Imaging System is similar in technological characteristics and intended use to the Eclipse 1.5T MR system and the PowerDrive 350 (PD350) Option. The following table has been created to demonstrate their substantial equivalence.

Substantial Equivalence Chart

Parameter	Infinion 1.5T MR Imaging System	Predicate Device – Marconi Eclipse 1.5T System (K964626) & PD350 Option (K002415)
Computer Subsystem		
Display/database system:	Single color LCD flat panel display for system operation and image reviewing, workstation tower, moveable keyboard, mouse and CD-ROM. Allows for simultaneous scanning and image reconstruction/manipulation. Image storage via magnetic or optical disk.	Single greyscale monitor for system operation and image reviewing, workstation tower, moveable keyboard, mouse and CD-ROM. Allows for simultaneous scanning and image reconstruction/manipulation. Image storage via magnetic or optical disk.
Scan/reconstruction hardware:	Standard image reconstruction rate of 50 ips. Optional packages available for increased rates.	Standard image reconstruction rate of 10 ips. Optional packages available for increased rates.
Network communications:	Same.	Display/Database computer and scan reconstruction hardware connected together by a dedicated Ethernet communications system. Second Ethernet interface for communication with systems on the external network. Ethernet communications link complies with DICOM v3.0 to allow image transfer to other MR, CT, Nuclear, workstation systems and cameras.
Gradient Subsystem		
Gradient Coils:	Water-cooled self-shielded gradient system with flared design to improve openness of system.	Water-cooled self-shielded gradient system for all performance levels.
Max. Gradient Strength:	20 or 30 mT/m	16, 20, 27 or 30 mT/m
Max. Slew Rate:	45, 60 or 120 mT/m/msec	25, 40, 72 or 120 mT/m/msec
Max. Performance Levels / Peak Strength	30 or 50 mT/m	
Max. Performance Levels / Slew Rate	45, 100 or 200 mT/m/msec	
Gradient Amps:	200 A RMS, 440 A peak, 700 V, or 200 A RMS, 440 A peak, 1400V	150 A RMS, 300 A peak, 400 V, or 270 A RMS, 440 A peak, 600 V, or 200 A RMS, 400 A peak, 1200V

Parameter	Infinion 1.5T MR Imaging System	Predicate Device – Marconi Eclipse 1.5T System (K964626) & PD350 Option (K002415)
RF Subsystem		
DTR Spectrometer:	Two channel transmitter and four receiver channels. Four additional receive channels are available as an option. Includes fast sampling ADC and additional digital filtering.	Single channel transmitter and receiver. Three additional receive channels are available as an option. Includes fast sampling ADC and additional digital filtering.
RF Amplifiers:	Two frequency RF amplifiers combined with an output power of 16 kW.	Single frequency RF amplifiers with an output power of 25 kW.
Body Coil:	60 cm, 24 rung, quadrature multi-conductor transmit/receive coil.	61 cm, 20-rung, quadrature multi-conductor transmit/receive coil.
Head Coil:	Quadrature multi-conductor receive only. Split-top design.	Quadrature multi-conductor receive only. Sled design.
Receive Only Coil Connection:	Same. Three connections on couch: 1 for ISA, 2 for other coils.	All receive only coils plug into single couch RF connector.
Transmit/Receive Box:	Four or eight receive channels available with system.	Four receive channels in system.
Optional Receive Only Coils	The following Eclipse system coils will also be compatible with the Infinion system. Large Joint Coil Small Joint Coil Quadrature Wrist Coil Shoulder Phased Array Cardiac Phased Array Volume Extremity Coil Flexible Body Array Additional new Multi-Mode Array coils provided with the Infinion system include: Integrated Spine Array (ISA) Anterior C-Spine Posterior C-Spine Head coil	Large Joint Coil Small Joint Coil Volume Neck Coil Quad Spine Coil and Positioner General Purpose Flex Coil Bilateral TMJ Coil (Linear and Phased Array versions) Bilateral Breast Coil C/T/L Phased Array Pelvic Phased Array Head-Neck Vascular Phased Array Flexible Body Coil (Quadrature and Phased Array versions) Quadrature Wrist Coil Shoulder Phased Array Quadrature Lower Extremity Coil Cardiac Phased Array Hammersmith Endocavitary Coils Coil Combiner Peripheral Vascular
Magnet Subsystem		
Magnet Type:	Same.	1.5 T active shield superconducting magnet.
Patient Handling		
Patient couch:	Computer controlled dockable couch with 200 kg weight capacity. Integrated 3-position arm board, IV hanger and ISA.	Computer controlled patient transport system with 200 kg weight capacity.
Patient positioning:	Same laser positioning marker. Additional automated stepping capabilities.	Laser positioning marker for accurate placement of patient at isocenter.

Parameter	Infinion 1.5T MR Imaging System	Predicate Device – Marconi Eclipse 1.5T System (K964626) & PD350 Option (K002415)
Patient communication, ventilation and illumination:	Same.	Two-way intercom system and hand-held audio alarm. Indirect DC lighting to illuminate the bore.
Magnet Enclosure		
Magnet Façade:	Cylindrical fiberglass enclosure with flared front and rear tunnel liners to improve openness of system.	Cylindrical fiberglass enclosure.
Controls:	LCD display above bore capable of displaying system status and gating signals. Two keypads on either side of bore for system controls.	LED display capable of display system status. Two keypads on either side of bore for system controls.
Power Distribution Subsystem		
Subsystem components:	Same.	Isolation transformer, transient suppression circuitry, and power distribution center all contained in a single cabinet.
Operating Software		
Base Software:	LINUX - X Windows based operating software. Graphical User Interface - windows and multi-tasking capability provided. Able to switch between on-going tasks.	UNIX - X Windows based operating software. Graphical User Interface - windows and multi-tasking capability provided. Able to switch between on-going tasks.
Operational Features:	Same SCAN, VIEW and FILM capabilities. Additional iPilot functionality for interactive scan setup.	SCAN capabilities include: Pilot positioning on three different reference images. Preloaded anatomical protocol categories. VIEW capabilities include: Multi planar reconstruction and curvilinear reformatting. FILM capabilities include: ability to set film formats and load print queue directly from Display/Database computer.
Software Options:	All software options are compatible with Infinion system. Additional functionality added to Cardiac option.	Angiography Cardiac Diffusion-Weighted MR Imaging Echo Planar Imaging Gradient-Recalled Spin Echo Image Post-processing Techniques iPass Bolus Tracking Quantitative Flow Spectroscopy Variable Fast Spin Echo ProPak

Parameter	Infinion 1.5T MR Imaging System	Predicate Device – Marconi Eclipse 1.5T System (K964626) & PD350 Option (K002415)
Standard Imaging Sequences		
2DFT:	Same.	Field Echo, Spin Echo, Multiple Echo, Inversion Recovery FAST, RF-FAST, CE-FAST and FSE.
3DFT:	Same.	FAST, FSE, RF-FAST and CE-FAST.
Acquisition and Reconstruction Techniques		
Available Features:	Same.	Multi-angle oblique, presaturation, phase conjugate symmetry, TrueRes and TrueSlice.
Time Varying Magnetic Field		
Normal Operating Mode:	Same.	dB/dt ≤ 40 T/s (See K002415)
First Controlled Operating Mode:	Same.	40 T/s < dB/dt ≤ 80 T/s (See K002415)
Radiofrequency Absorption		
Normal Operating Mode:	Same.	Limited to a maximum level of 1.2 W/kg.
First Controlled Operating Mode:	Same.	Limited to a maximum value of 3.2 W/kg.
Acoustic Noise		
Typical:	99 dBA (average) 12.3 dB (peak)	94.5 dBA (average) 107.3 dB (peak) (See K002415)
Worst Case:	117.9 dBA (average) 127.2 dB (peak)	114.7 dBA(average) 123.3 dB (peak) (See K002415)
Intended Use and Indications for Use		
	Same.	The Eclipse System is indicated for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2001

Mr. Duane Praschan
Manager, Regulatory Affairs
Marconi Medical Systems
595 Miner Road
HIGHLAND HEIGHTS OH 44143

Re: K003853
Infinion 1.5 MR Imaging System, Model MRI 100
Dated: November 30, 2000
Received: December 12, 2000
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LNH

Dear Mr. Praschan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003853

Device Name: Infinion 1.5T MR Imaging System

Indications for Use:

The Infinion 1.5T MR Imaging System does not change the existing indications as defined below.

The Infinion 1.5T MR Imaging System is indicated for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003853